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Superelastic Nitinol for Medical Devices

Thomas W. Duerig, Alan R. Pelton, and Dieter Stöckel

Superelastic nickel-titanium (Ni-Ti), or nitinol, alloys are becoming integral to the development of a variety of new medical products. The enormous elasticity of these alloys is the most dramatic advantage afforded by this material, but by no means the only or most important one. Also discussed in this paper are features such as biocompatibility, kink resistance, constancy of stress, physiological compatibility, shape-memory deployment, dynamic interference, and fatigue resistance. Each of these properties is discussed and highlighted through examples of medical products including stents, filters, retrieval baskets, and surgical tools.

Superelasticity refers to the unusual ability of certain metals to undergo large elastic deformation. Although the term is used synonymously with pseudoelasticity, we adhere to the definition that pseudoelastic alloys need only show nonlinear unloading behavior whereas superelastic alloys must exhibit an inflection point. An inflection point in the unloading behavior indicates the presence of an unloading plateau, or a strain range of approximately constant stress. As we will see, this is an important distinguishing feature for medical applications. While many metals exhibit superelastic effects, only Ni-Ti alloys appear to be chemically and biologically compatible with the human body. Although a number of Ni-Ti ternary alloys have been introduced, none has been objectively shown to be superior to simple binary Ni-Ti with between 50.6 and 51.0 atomic percent nickel.

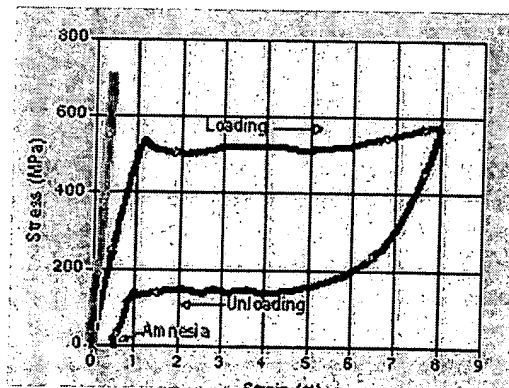


Figure 1. Stress-strain curve for a Ti-Ni alloy (atomic percent Ni) tested at 10°C above its transformation temperature. A typical elastic loading/unloading curve for stainless steel is shown in light gray.

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The stress-strain behavior of superelastic nitinol is illustrated in Figure 1. The detailed mechanistic origins of superelasticity have been discussed extensively elsewhere.^{1,2} The most superficial advantage of superelastic alloys is that up to 11% springback or elastic recovery is realized, as compared with 0.5% in the most commonly used medical material, stainless steel. Of course, superelasticity only occurs over a relatively narrow temperature range above the austenite finish (A_f) temperature--optimum performance is found at the A_f temperature, and performance steadily deteriorates until the martensite deformation temperature, at which point all indications of superelasticity have vanished. It should be noted that many designs have complex geometries and strain distributions, and that the A_f increases with strain. For example, an 8% strain will increase A_f by approximately 1°C. Thus, optimum superelasticity requires that one completely understand the strain to which the part will be subjected.

Strengthening the alloy--through a combination of cold work, aging, and annealing--provides it with optimum performance over approximately a 40°C window, starting at A_f temperature. Still, the functional temperature range is too narrow for most industrial and consumer applications--automobile springs, for example, generally require elasticity from -30° to 200°C. Moreover, the stiffness of a superelastic device changes with temperature according to the Clausius-Clapeyron equation, at a rate of approximately 48 MPa/°C. The variability of superelasticity with temperature is, by far, the factor most limiting to its general use. Fortunately, mammalian bodies have a relatively constant temperature well suited to the use of superelasticity. Furthermore, the 37°C temperature of humans is easily achieved in Ni-Ti without having to go to brittle Ni-rich alloys, or to very Ti-rich alloys. Thus, the vast majority of successful superelastic applications are of a biomedical nature.

ADVANTAGES OF SUPERELASTICITY IN MEDICINE

Material selection is seldom based on a single attribute, but rather on a combination of several. Similarly, the tremendous elasticity of nitinol is only one of the many unique characteristics favoring its use. To highlight the value of superelastic nitinol to the medical

industry, the following 10 specific device characteristics will be discussed and illustrated: the design of a range of medical devices: elastic deployment, biocompatibility, kink resistance, constancy of stress, physiological compatibility, thermal deployment, dynamic interference, fatigue resistance, hysteresis, and MRI compatibility. Some of these properties, such as elastic deployment, are obvious to designers, whereas others, such as dynamic interference and hysteresis, are not. Still, all provide potentially important grounds for application of nitinol.

ELASTIC DEPLOYMENT

Figure 1 compares typical stress-strain curves for stainless steel and nitinol. The most apparent difference is that elasticity, or "springback," is some 20 times greater in nitinol than in stainless steel. A large variety of products are now on the market that use this particular design feature, but perhaps the newest and most interesting is the atrial septal defect occlusion system (ASDOS) (Osypka Medizintechnik, Rheinfelden, Germany).³ This device is the first to allow nonsurgical repairs of occlusions, or holes, in the atrial wall of the heart. At the time of writing, at least five procedures have been published, treating defects ranging in diameter from 20 to 35 mm. A transcatheter method is used with the ASDOS procedure conducted through two catheters, in this case 10 french (~3.5 mm) in diameter.



Figure 2. The atrial septal-defect occlusion device used to seal holes in the heart wall. Figure 2a shows the two umbrella-shaped patches that are placed on either side of the defect. Figure 2b shows the installed halves, screwed together, after positioning.

The actual device comprises two small umbrellas consisting of five nitinol wire loops supporting webs of microporous polyurethane (see Figure 2a). The two umbrellas are introduced into the body while folded into two catheters, and are positioned one each on either side of the defect area. A guidewire passing directly through the hole is used to ensure that the catheters and umbrella devices are positioned correctly. Once positioned, the umbrellas are pushed forward from their catheters and screwed together using a special torquing device. The resulting sandwich forms a patch, occluding the atrial defect. Available umbrella diameters range from 20 to 65 mm. Although it is too early to convincingly evaluate the success of this particular product, it illustrates well the concept of elastic deployment that no other known metal would survive such an application.

The compliance, or elasticity, of an engineered component depends of course on design as well as on the inherent elasticity of the material used. For example, one can increase the compliance of a coil spring by adding coils, but this would increase weight and size. Material properties dictate the total elastic energy stored in the device, while design can only dictate how one partitions the total stored elastic energy of a given amount of material (favoring either force or motion). The use of nitinol allows one to design stiffer, more compact devices and more elastic devices by increasing the elastic storage by a factor of nearly 10.

To highlight this, we can look at the Homer Mammalok (Mitek, Westwood, MA), which radiologists use to "mark" the location of a breast tumor. This device consists of a 0.40-mm diam nitinol wire hook and a stainless-steel cannulated needle.⁴ The wire hook is inserted into the needle cannula, and the cannula is inserted into the breast and adjusted until its distal end is verified to be at the site of the tumor. The hook is then pushed out, reforming its hook configuration, with a radius of 9 mm. The device can be withdrawn, repositioned, and redeployed as required until the position has been correctly marked for the surgeon. While inside the cannula, the strain in the hook is estimated to be in excess of 8%--far more than can be obtained with stainless steel. The same device made from stainless steel would require a reduction in the wire diameter from 0.40 to 0.05 mm, assuming the hook geometry is to remain fixed. Such a fine wire would be far too flimsy to anchor the hook effectively, and could allow inadvertent and undetected transection. Alternatively, a stainless-steel wire of the same 0.40-mm diam could only form a hook of 50-mm radius in contrast to the 9-mm radius possible with nitinol. In either case, the hook would most likely again fail to firmly hold position.

Endoscopy is another field that has taken advantage of elastic development.⁵ As the number of endoscopic procedures increases, so does the need for increasingly complex tools which must pass through a narrow trocar. Superelasticity allows one to pass a rather complex instrument through a straight trocar, and enables the instrument to elastically return to the deployed configuration once through. Instruments include suture passers, retractors, graspers that operate at right angles to the trocar, and retrieval bags. Such surgical graspers and scissors can be designed without hinges and other complex parts that make cleaning and sterilization difficult or impossible (an example will be introduced in Figure 8).

BIOCOMPATIBILITY

Nitinol alloys contain more nickel than does their primary competitor, 316L-grade stainless steel. This rather obvious statement has little meaning to metallurgists, but unfortunately has too much meaning to nonspecialists, who recognize that nickel itself is considered toxic. As nitinol oxidizes, it forms a TiO₂ layer, with small islands of pure nickel on the surface, or, depending on the treatment, with no nickel present at the surface.⁶ Polarized light testing in Hank's solution has repeatedly shown that nitinol is chemically more stable and less corrosive than stainless steel, but less stable than pure titanium.⁷ Extensive in vitro testing and experience indicates that nitinol is highly biocompatible--more so than stainless steel.

steel. Nitinol implants exist in dentistry, orthopedics, and many other branches of medicine with large numbers of permanent implantations reported in Japan, Germany, China, Russia, dating back to the early 1980s.⁸ Most significantly, FDA has cleared the way for sale of the first Class III nitinol implant for use in the United States, specifically the vena cava filter, developed by Nitinol Medical Technologies (Boston, MA) (see Figure 3). FDA has similarly approved the Mitek bone anchor system, another permanently implanted nitinol device.

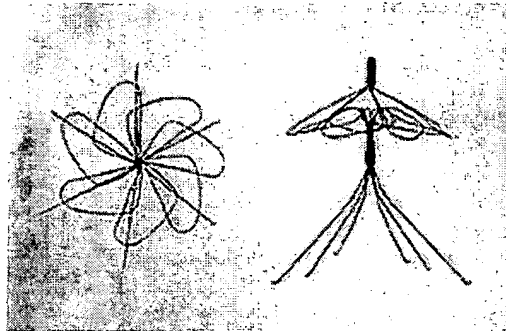


Figure 3. A Simon filter, shown in longitudinal and transverse views of the deployed state.

A detailed discussion of biocompatibility and all its nuances is certainly beyond the scope of this article, and readers are referred to several reviews of the field.^{8,10} One should be cautioned, however, to carefully observe testing and material conditions before relying on published information, as a great deal of the literature is inadequate in defining standard test chemistries, thermomechanical treatments, and, most importantly, surface treatment. Work on nitinol biocompatibility must be performed before it can be firmly established how biocompatible the material is, and how performance can be optimized. Still, regarding biocompatibility issues, it is clear that nitinol will outperform stainless steel in most environments.

KINK RESISTANCE

For the most part, nitinol wires cannot be kinked. To some extent, this design property stems from the increased elasticity cited above, but it is even more a result of the shape of the stress-strain curve. When strains are locally increased beyond the plateau strain, stresses increase suddenly. This causes the incremental strain to partition to the area of lower strain, instead of increasing the peak strain itself. Thus kinking, or strain localization, is prevented by creation of a more uniform strain than would be realized in a conventional elastic-plastic material.

The first applications to take advantage of this feature were angioplasty guidewires, which must be passed through tortuous vessel paths without kinking. Even very small permanent bends in the wire cause "whipping" and destroy its ability to be steered. The ASDOS procedure described earlier, for example, employs nitinol guidewires to place the catheter correctly. There can be little doubt that nitinol has played a key role in the success of angioplasty procedures.

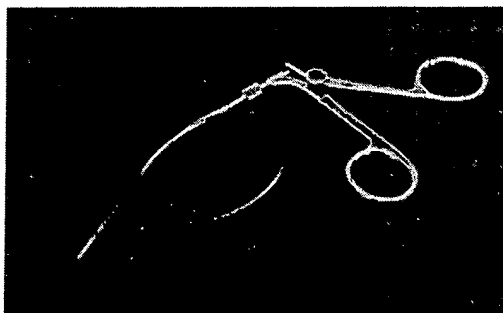


Figure 4. A 1-mm-diam urological grasper (Tuttlingen, Germany) demonstrates kink resistance. The shaft comprises a nitinol wire concentrically placed in a nitinol tube; the distal end is a stainless-steel grasper, which opens to an approximately 90° included angle.

More recently, retrieval baskets have used nitinol kink-resistant shafts along with a

superelastic basket to retrieve stones from kidneys, bladders, and bile ducts. Perhaps the newest and most interesting application is in extremely small-diameter instruments. For example, the 1-mm-diam grasper depicted in Figure 4 is composed of a very-thin-wire nitinol tube with a nitinol wire inside. Together, they are able to be bent around radii less than 3 cm without kinking, and still allow for opening and closing of the distal grasper without increased resistance. Stainless-steel or other metallic instruments would likely be destroyed by even very slight mishandling, whereas the nitinol device continues to function smoothly even while bent around tortuous paths.

CONSTANCY OF STRESS

Another important feature of superelastic materials is that their unloading curves are nearly identical over large strains. Thus, the force applied by a superelastic device is determined by temperature, not by the strain as in conventional Hookean materials. Because body temperatures are substantially constant, one can design a device that applies a constant stress over a wide range of shapes.

The orthodontic archwire was the first product to take advantage of this property. Stainless steel and other conventional wires are tightened by the orthodontist--often to the point of causing pain. As treatment continues, the teeth move and the forces applied by stainless steel quickly relax. This causes treatment to slow, retarding tooth movement. Retightened by the orthodontist, the process is repeated, with only a narrow optimum treatment period per visit. In contrast, nitinol wires are able to move with the teeth, applying a constant force over a broad treatment time and tooth position. Different grades of wire stiffness are available, allowing the orthodontist to "program" the stress and ensure that treatment will proceed properly, with fewer visits and less pain. Nitinol archwires were introduced in the late 1980s; we estimate that over 30% of the archwires used today are nitinol. Another popular application is superelastic eyeglass frames--the first successful nitinol consumer product.

PHYSIOLOGICAL COMPATIBILITY

Stainless steel, titanium, and other metals are very stiff relative to biological materials, yielding little if at all in response to pressures from surrounding tissue. The extraordinary compliance of nitinol clearly makes it the metal that is most similar mechanically to biological materials. This improved physiological similarity promotes bony ingrowth and proper healing by sharing loads with the surrounding tissue, and has led to applications such as hip implants, bone spacers (see Figure 5), bone staples, and skull plates. This latter application is particularly interesting in that it utilizes porous nitinol, which further promotes the advantages of the material, particularly bony ingrowth.¹¹ Combustion synthesis--using the heat of fusion to "ignite" the formation of Ni-Ti from nickel and titanium--has been shown to be an effective way of producing a porous "sponge" of nitinol, with densities of 40 to 90%. The sponge maintains superelastic and shape-memory properties, has a mechanically reduced modulus of elasticity, accelerates bony ingrowth, and offers in vivo adhesion to surrounding tissue. The application of these particular devices was pioneered in Russia, and warrants a good deal more attention than it has thus far received in the United States.

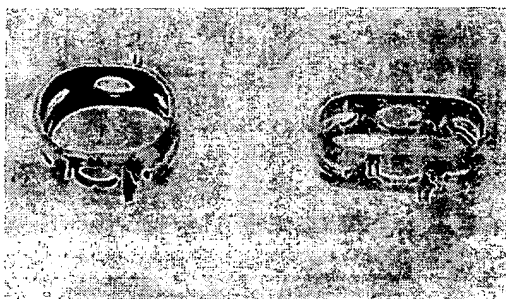


Figure 5. Spinal vertebrae spacer shown in its martensitic state (left) and deployed superelastic state (right). The characteristics of nitinol permit more rapid recovery due to the similarity of mechanical properties between the implant and surrounding tissue.

It should be noted, however, that the physiological compatibility discussed here comes at a price: calculational complexity. Conventional metals are linearly elastic, and readily lend themselves to both analytical and finite element analysis (FEA) methods. Nitinol, like biological materials, is much more difficult to model: not only is its behavior nonlinear, there is a hysteresis, a strong temperature dependency, and a permanent set. To make matters worse, the latter two properties are strain-dependent. A great deal of work is currently under way to improve the applicability of modeling methods to these types of materials, but much more is needed. As yet, the authors are unaware of a single FEA package that is able to deal with all of the above characteristics. Given that FEA is both an important tool for designers and a required element in FDA submissions, we think this is an area warranting (but not currently receiving) substantial R&D funding.

THERMAL DEPLOYMENT

Another unique attribute of superelastic devices is that they can be deployed using the shape-memory effect. One example is the vena cava filter discussed earlier. The device is received by the physician preloaded in a catheter and in its martensitic state. Flushing with chilled saline solution through the catheter keeps the device in the martensitic phase as it is positioned to the deployment site. When released from the catheter, the device is, by its warmer surroundings, recovers its "preprogrammed" shape, and becomes a superelastic device. The precise moment at which the device becomes superelastic is unclear nor important--very likely this occurs before it is fully released from the catheter. Chilled saline only acts to reduce the forces applied by the filter against the catheter, making deployment easier. It is proper to consider the device to have completed the memory effect when heated above A_f , even when the filter is still fully constrained within the catheter, since the equilibrium shape of the device has already been recovered.

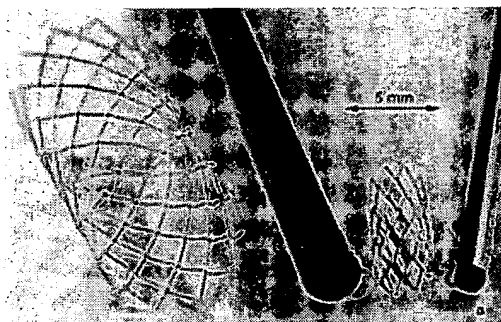
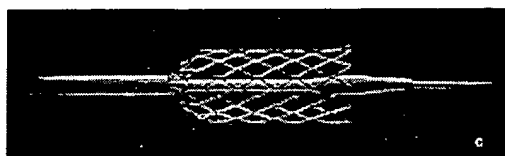
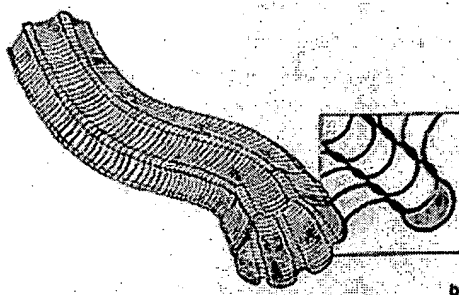


Figure 6. Stents made from nitinol tubing (a receiving a great deal of interest, though with stents, such as the Microvasive device show are already in use in the United States. Dep. of an Angiomed stent (from tubing) is shown.



The most celebrated superelastic medical devices are self-expanding stents, used to line the inside circumference of a tubular passage such as an esophagus, bile duct, or blood vessel (see Figure 6). Probably the most interesting area of application is in the

cardiovascular system, as a follow-up to balloon angioplasty. The placement of a stent has been shown to significantly decrease the propensity for restenosis. Like the vena caval filters, these devices are generally permanent implants, deployed through a catheter using the shape-memory effect. Even in the case where no chilling is done to assist deployment, one should consider such devices to be thermally deployed since their equilibrium shape is restored by warming to body temperature. Cardiovascular stents currently available in the United States are made of stainless steel, and are expanded against the vessel wall by plastic deformation caused by the inflation of a balloon placed inside the stent. Nitinol stents, on the other hand, are self-expanding--instead of being deformed to the vessel diameter, they expand by simply returning to their equilibrium, or nondeformed, shape. Self-expanding stents are now available in Europe, and, for certain applications, in the United States. Nitinol stents can be made from wire, laser-cut sheet, or tubing. Because overlaps and irregularities can lead to thrombogenicity, the most promising devices appear to be those cut from tubing. Of course, one might cut the expanded or the contracted shape depending on the specific design requirements. Stents are also made from sheet metal that is either welded or mechanically joined into a cylinder after cutting. Typically, the diameter ratio of the two states is between 300 and 600%. Surface finish is very important to reduce thrombogenicity and biocompatibility, and plays a key role in device production.

Anticipated advantages of nitinol stents over current balloon-expandable stents include greater resistance to crushing in exposed vessels (such as the femoral or carotid artery), lower bending stresses when situated in tortuous paths, more flexible delivery systems, the ability to scaffold cross sections other than circles, and the elimination of acute recoil. It is certain that nitinol will become the preferred material for many devices, but only time will tell if self-expanding stent technology will indeed spearhead the next generation of minimally-invasive interventional treatment, as many physicians and device manufacturers believe.

DYNAMIC INTERFERENCE

Stents benefit from another important feature of superelasticity: dynamic interference. To illustrate this, compare a self-expanding nitinol stent with a balloon-expanded, stainless steel stent. Following balloon expansion, the balloon is deflated, causing the stent to spring back towards its smaller, undeformed shape. This type of loosening is called acute springback, and is clearly undesirable. In order to fill a 5-mm lumen, the stent might have to be expanded to 6 mm so that it springs back to 5 mm. This has the potential to distort the vessel, and can lead to restenosis. In contrast, the nitinol stent expands directly to its preconditioned diameter, with no recoil. After deployment, it continues to gently push outward against the vessel wall, helping to prevent undesirable changes in position or shape movements in the vessel. Moreover, it will try to fill an oblong or irregularly shaped section, whereas a balloon-expanded stent will always adopt the round shape of the balloon.

Dynamic interference also means that there will be a permanent force acting in the outward direction, even if the vessel should increase in diameter over time. Though this may be beneficial in maintaining the location of the stent in the vessel, it remains unclear whether there will be long-term side effects. It is possible that this continuous opening force could cause irritation, restenosis, or undesirable creep effects. Current designs try to maintain this force at very low levels.

FATIGUE RESISTANCE

Because of the unusual way that nitinol deforms, it has a fatigue behavior that is quite atypical of metals in general. Fatigue environments can be divided into two distinct categories: strain controlled and stress controlled. The former group describes environments in which the device is alternately deformed between two set shapes, while the latter describes the influences of cyclic loading. To illustrate the difference, compare the fatigue behavior of a rubber band and a loop of steel wire. In a stress-controlled environment, the steel wire lasts far longer than does the rubber band. In a strain-controlled environment (e.g., alternating stretching and releasing), the rubber band will certainly outperform the steel.

Nitinol is much the same: in strain-controlled environments it will dramatically outpace conventional metals. In stress-controlled environments, however, it may well fatigue. Practically speaking, most fatigue environments in the body are a combination of the conditions, making it difficult to make summary judgments concerning fatigue. In general, the very compliant nature of biological materials tends to place them in the direction of strain-controlled fatigue, where nitinol will excel.

One example of an obvious strain-controlled application is in pacemaker leads, which are made of a conductive metal that can survive very high numbers of flexing motions without breaking. Research on candidate materials has shown that nitinol has superior strain-controlled properties. Certainly a great deal of fatigue testing of stents is being done; although results have been published, it does appear that nitinol performs at least as well as stainless steel.

HYSTERESIS

Stresses applied by superelastic components are path-dependent: that is, the stress applied by a superelastic device is likely to be more dependent upon whether one is loading or unloading than on the position of the device itself. This biased stiffness is illustrated in Figure 7, which charts the expansion of a stent. A superelastic stent should provide only a very light outward force against a vessel wall, and at the same time be resistant to crushing--compliant in one direction, and stiff in the other. This is a very important feature in stent design. As pointed out earlier, opening forces are "live," and they will forever continue to act to open the lumen. These opening forces must be very low to avoid damage (through creep) of the vessel wall. On the other hand, it is important to have a device that resists the forces tending to close the lumen. Nitinol can satisfy both of these conditions. Also note that, if the stent is later reexpanded to a larger diameter, the loading curve in Figure 7 will be displaced to the left, but the stiffness will remain the same.

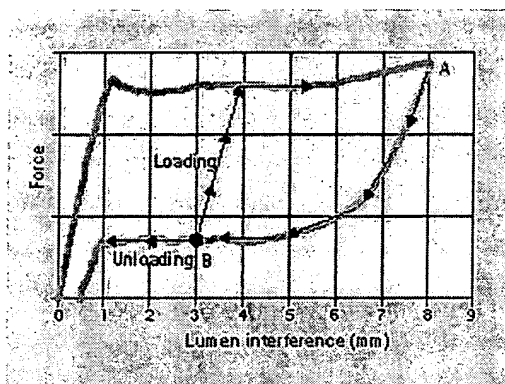


Figure 7. Principle of biased stiffness illustrated by a stent. The gentle pressure against the vessel wall is controlled by the unloading arrows, but resistance to the vessel is resisted by the stiffness indicated by the loading arrows.

MRI COMPATIBILITY

Nitinol provides a very clear, crisp MRI image. Figure 8 shows an MRI image of a nitinol grasper used in gall bladder surgery, together with a matching photograph of the same end. An identical grasper made from stainless steel would be completely unrecognizable. Although there are no commercially available products that take advantage of this feature, it has great potential importance, particularly with the advent of open-MRI procedures. Applications for needles and instruments are currently being explored.

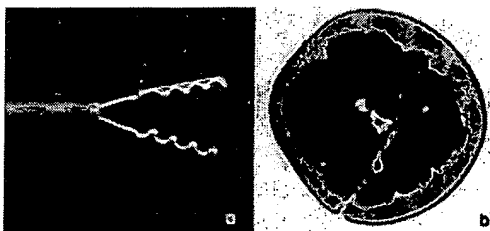


Figure 8. A nitinol grasper, designed for endoscopic gall bladder surgery, is shown optically (a) and in an MRI image while testing in a grapefruit (b).

CONCLUSION

Nitinol alloys provide a unique range of characteristics not found in any other material. A combination of properties makes them particularly interesting for devices used in interventional procedures. Self-expanding stents, for example, benefit from thermal change for deployment, superelasticity for shape recovery after deformation, dynamic hysteresis for perfect fit, and hysteresis for biased stiffness. Moreover, nitinol alloy offers biocompatibility, magnetic-resonance visibility, and fatigue resistance.

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